Your Liver. Your Life.

An Introduction to Clinical Trials

American Liver Foundation
Support Guide

An Introduction to Clinical Trials

You may have heard the term clinical trial and have questions about what a clinical trial is and how it works.

The American Liver Foundation (ALF) is here to help. This guide contains information on what a clinical trial is, who is involved, how the process works, potential risks and benefits, and much more.

Learn as much as you can about clinical trials. Deciding to participate in a clinical trial is a team effort! It involves talking to your doctor, your family and caregivers, and the clinical trial team to see if it is an option for you.

The American Liver Foundation's mission is to facilitate, advocate, and promote education, support, and research for the prevention, treatment, and cure of liver disease.

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Clinical Trials Overview

Clinical Trials

A clinical trial is a medical research study conducted to find answers to health questions.

Clinical trials are often conducted to evaluate new medications, a combination of medications, or new ways to use current treatments. Clinical trials are also conducted to evaluate new tests, equipment, and procedures for diagnosing and detecting health conditions and to find vaccines to prevent illnesses.

Before an experimental treatment can be tested in a clinical trial, it must have shown benefit in laboratory testing, animal research studies, or research in a small group of humans. Clinical trials are required to follow the same ethical and legal guidelines as standard medical practice to protect the safety of participants.

Every clinical trial in the United States must be approved and monitored by an Institutional Review Board (IRB) to make sure the potential risks to participants are as low as possible. Every institution that conducts clinical trials has an IRB. An IRB is a committee of health care professionals and community members that do not have connections to the specific clinical trial. The IRB committee allows for unbiased decisions to be made about the clinical trial and patient safety.

Clinical Trial Eligibility

Every clinical trial has guidelines and requirements about who can participate.

Some clinical trials may look only for people of a certain age, gender, race, ethnicity, or people with a specific disease, stage of disease, or treatment history. Other clinical trials may be looking for people without serious health conditions.

Clinical Trial Protocol

A protocol is the clinical trial plan that explains the purpose and process of the trial. A protocol will include information such as:

- Who can participate
- How many people will participate
- What the treatment plan involves
- Type and frequency of tests
- How the results will be measured
- Reasons why the clinical trial may be stopped
- Reasons why the researchers may stop giving the experimental treatment to a participant
- Known and likely side effects of the experimental treatment
- Potential benefits of the experimental treatment

Clinical Trial Informed Consent

Informed consent is the process of learning about the clinical trial before deciding to participate. Before someone can participate in a clinical trial they must review and sign an informed consent form. As part of the informed consent process, participants also will be able to review the trial protocol with the clinical trial team. A clinical trial team consists of doctors, nurses, social workers, and other healthcare professionals.

The informed consent form will include the following information:

- Clinical trial process, including tests that may be conducted
- Known risks and benefits of experimental treatment
- Length of clinical trial
- Clinical trial contact information

Even after signing the informed consent form, participants may choose to stop participating in the clinical trial at any time.

Clinical Trial Process

The process for a clinical trial depends on the type of clinical trial.

Generally, at the beginning of the clinical trial, each participant's health is checked and the team provides instructions to the participants. The team will then monitor participants closely during the clinical trial and will follow up with participants after the clinical trial is completed.

Clinical Trials Phases

Clinical trials are conducted in phases. Each phase of the clinical trial has a different purpose.

- Phase 1: experimental treatment is given to a small group of people (20-80) for the first time to evaluate its safety, dosage range, and side effects
- Phase 2: experimental treatment is given to a larger group of people (100-300) to evaluate its safety and effectiveness
- Phase 3: experimental treatment is given to large groups of people (1,000 – 3,000) to confirm its effectiveness, monitor side effects, compare to current treatments

If the experimental treatment works well in a Phase 3 trial, researchers can submit an application to the U.S. Food and Drug Administration (FDA) asking permission to make the treatment available to the public. The FDA approval process generally takes about a year.

In some cases, research continues even after the FDA has approved a treatment. The FDA can ask researchers to conduct a Phase 4 trial.

- Phase 4: collect information on experimental treatment's long term safety and effectiveness

Other clinical trial terms you may hear:

Placebo: A placebo is an inactive pill, liquid or powder that looks like the experimental treatment but has no effect on the body. In some clinical trials, experimental treatments are compared with placebos to evaluate the effectiveness of the experimental treatment.

Control group: A control group consists of participants who receive either standard treatment or a placebo and serves as a comparison group to measure the effectiveness of the experimental treatment other participants are receiving. Participants are randomly assigned to control or non-control groups.

Frequently Asked Questions

What are the potential benefits of participating in a clinical trial?

Potential benefits of clinical trials include:

- Access to new research treatments
- Access to specialists and expert care
- Contribution to medical research that can help others

What are the potential risks associated with participating in a clinical trial?

Potential risks associated with clinical trials include:

- Serious side effects
- Unsuccessful treatment outcome
- Ineligibility to participate in other trials

Are clinical trials covered by health insurance?

Health insurance coverage of clinical trials varies by insurance company, plan, and location of clinical trial. Some health insurance companies or plans do not cover any clinical trial costs; others only cover costs associated with routine care. Some cover all patient care costs associated with clinical trials.

Currently 30 states have laws or agreements requiring health insurance plans to cover at least the cost of routine care when participating in clinical trials. To find out more about the regulations in your state visit: http://www.cancer.gov/clinicaltrials/developments/laws-about-clinical-trial-costs.

Contact your insurance company to learn more about your insurance plan's coverage of clinical trials. Talk to the clinical trial coordinator about all the patient care costs associated with the clinical trial.

How do I participate in a clinical trial?

The first step is to talk to your doctor to see if clinical trials are an option for you.

If clinical trials are a good option for you, contact the clinical trial coordinator to see if you meet the requirements for the clinical trial.

If you meet the initial requirements, you will be scheduled for a pre-trial screening where tests will be done to help researchers decide if you are a candidate for the trial. The pre-trial screening also will be an opportunity for you to learn more about the clinical trial including its benefits and risks.

Where can I find information about clinical trials in my area?

For information on clinical trials in your area:

- Search the National Institutes of Health's clinical trials website: http://clinicaltrials.gov
- Talk to your healthcare provider about clinical trials that you may be eligible for
- Contact patient advocacy organizations for information on clinical trials in your area
- Contact local medical institutions to learn about upcoming clinical trials

Questions to Ask Your Healthcare Provider

1. Are clinical trials an option for me? If so, what types of clinical trials am I eligible for?
2. Do you know of clinical trials that I can participate in that would be a good option for me?
3. What are the benefits of participating in a clinical trial?
4. What are the risks associated with participating in a clinical trial?
5. If I am assigned to a placebo group will the treatment be available to me after the trial?
6. What symptoms or signs should I be looking for to know if I am having positive or negative side effects to the experimental treatment?
7. How will participating in a clinical trial affect my other health conditions?
8. Can I continue to take my current medications if I participate in the clinical trial?
9. Do I follow up with you during the trial or the clinical trial team?

Questions to Ask the Clinical Trial Team

1. What is the purpose of this clinical trial?
2. Why is this experimental treatment believed to be effective?
3. What are the benefits associated with this clinical trial?
4. What are the risks associated with this clinical trial?
5. How do the possible benefits and risks of this trial compare with my current treatment?
6. What short and long term impact will this trial have on my day to day activities?
7. What is expected of me if I participate in this clinical trial?
8. What kinds of tests are involved?
9. How long will the clinical trial last?
10. Is it possible that I may receive a placebo?
11. Will I need to pay for any part of this clinical trial?
12. How will I know that the experimental treatment is working?
13. What happens if my condition gets worse during the clinical trial?
14. If for some reason I need to stop my participation in this clinical trial, how do I communicate that and to whom?
15. Who will be responsible for my care?
16. Should I continue to see my own doctor during the clinical trial?
17. What type of long term follow up care is part of this study?
18. What happens at the end of the clinical trial?
19. Will I be told the results of the clinical trial? When?

Glossary

Clinical trial: A clinical trial is a medical research study conducted to find answers to health questions. Clinical trials are often conducted to evaluate new medications, combination of medications, or new ways to use current treatments. Clinical trials are also conducted to evaluate new tests, equipment, and procedures for diagnosing and detecting health conditions and to find vaccines to prevent illnesses.

Control group: A control group consists of participants who receive either standard treatment or a placebo and serves as a comparison group to measure the effectiveness of the experimental treatment other participants are receiving.

Double blind study: A double blind study is a clinical trial in which both the participant and clinical trial team do not know which participants are receiving the experimental treatment and which are receiving a placebo or standard treatment.

U.S. Food and Drug Administration (FDA): The Food and Drug Administration (FDA) is a government agency responsible for ensuring the safety and effectiveness of all medications, vaccines, medical equipment used for prevention, diagnosis, and treatment.

Informed consent: Informed consent is the process of learning about the clinical trial before deciding whether or not to participate. There is an informed consent form that all participants are required to review and sign if they want to participate in the clinical trial. The informed consent form will include information on the clinical trial process, including tests that may be conducted, known risks and benefits of experimental treatment, length of clinical trial, and clinical trial contact information.

Institutional Review Board (IRB): An Institution Review Board (IRB) is a committee of health care professionals and community members, who review, approve, and monitor clinical trials to make sure potential risks are as low as possible and that the clinical trial follows ethical and legal codes for medical practice.

Placebo: A placebo is an inactive pill, liquid or powder that looks like the experimental treatment but has no effect on the body. In some clinical trials, experimental treatments are compared with placebos to evaluate the effectiveness of the experimental treatment.

Protocol: A protocol is the clinical trial plan that explains the purpose and process of the trial. A protocol will include information such as who can participate, how many people will participate, what the treatment plan involves, type and frequency of tests, how the results will be measured, reasons why the clinical trial may be stopped, reasons why the researchers may stop giving the experimental treatment to a participant, known and likely side effects of the experimental treatment, and potential benefits of the experimental treatment.

Randomization: Randomization is a method used to randomly assign participants to treatment and/or control groups.

Single blind study: A single blind study is a clinical trial in which either the participant or the clinical trial team does not know if the participant is taking the experimental treatment.

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